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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,310	01/21/2000	Gary Stephenson	7922	5677

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THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
WINTON HILL TECHNICAL CENTER - BOX 161
6110 CENTER HILL AVENUE
CINCINNATI, OH 45224

EXAMINER

ROSE, SHEP K

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/11/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/489310

Applicant(s)

STEPHENSON P+G 7922

Examiner

SHOP ROSE

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on JUNE 20 2003
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 111; 453 O.G. 213.

Disposition of Claims

- ☐ Claim(s) 115/5 17520 2223 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 115/5 17520 2223 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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The finality of the January 9, 2003 office action is hereby withdrawn in view of an issue of obviousness-type double patenting presented by claims 1 to 24 of application 10/318,963; a "C/I/P" of this application as well as issues of 35 USC 112 (1st PAR) in claims 11 to 22 with respect to "KIT", and the "metes and bounds" (2nd PAR) of "ABOUT" as recited on lines 1 and/or 2 of claims 11, and 23, and the "metes and bounds" of (B) "information" as recited in claim 11 (last 2 lines).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 to 15, 17 to 20, 22 to 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "metes and bounds" of "KIT", "ABOUT" and (B) INFORMATION as recited in these claims are vague and indefinite.

Claims 11 to 15, 17 to 20, 22 to 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not provide any definition or "metes and bounds" for enabling the claim recited "ABOUT", "KIT" or (B)

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"INFORMATION" so that the public cannot determine the metes and bounds" of these claims, and can avoid infringing these claims.

Claims 23 to 31 misleadingly recite "treating dental erosion" when they mean no more than "protecting against" dental erosion by ingesting acidic beverages containing sodium hexametaphosphate, (or other polyphosphate). The public cannot determine how to avoid infringing the "metes and bounds" of these claims, (as compared to prior art acidic beverages containing sodium hexametaphosphate or other polyphosphate as stabilizing preservative, chelating sequestrant, etc.)

All the claims presented depend for their enablement on four (4) examples set forth on pages 22 and 23 of applicants' specification which was filed on January 21, 2000.

Each of the four examples has 0.1% of sodium hexametaphosphate, an encompassed of polyphosphate (N=21). Examples 1 and 2 contain citric acid, sufficient to titrate to a pH of 3.3, and are to a sweetened fruit juice beverage, and to a tea beverage; respectively. Examples 3 and 4 are also to sweetened fruit juice beverages, the pH of Example 3 is from about 2.9 to about 3.3.

Since the methods of "treating" "dental erosion" as recited in claims 23 to 31, by oral ingestion of such acidic beverages means no more than protecting against dental erosion, according to the recitals of page 4, lines 22 to 28, i.e. its preventing or prophylactic in nature, the beverage user being not one actually having dental erosion being "treated" these claims are highly misleading, and vague and indefinite. Under 35 USC 112 (2nd par), and are met or anticipated by any Pre January 21, 2000 reference

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describing 0.19% sodium hexametaphosphate in any sweetened acidic beverage, pH less than "about 5".

The "metes and bounds" or encompassed "scope" of these claims are "vague and indefinite" (35 USC 112, 2nd par.), USPTO Examiners must now reject on 35 USC 112 (2nd) Par grounds of rejection when the public cannot determine the "metes and bounds" of the patent's claims and take steps to avoid infringement.

Stephen Kunin's (Deputy Commissioner for Patent Examination Policy) January 17, 2002 Memorandum, effective immediately, [(Clarifying Office Policy with respect to rejections made under 35 U.S.C. 112, second paragraph). Advance notice of changes to MPEP 2173.02,].

Commissioner Kunin's January 17, 2002 Memorandum states that in reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim provides clear warning to others as to what constitutes infringement of the patent and therefore serves the notice function required by 35 USC 112, second paragraph, and, if the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph would be appropriate. The examiner must consider the claims as a whole to determine whether or not the claim apprises one of ordinary skill in the art of its "metes and bounds".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Memorandum

Date: January 17, 2003

TO: Technology Center Directors
Patent Examining Corps

From: Stephen G. Kunin
Deputy Commissioner for Patent Examination Policy

Subject: Advance notice of changes to MPEP § 2173.02 clarifying Office policy with respect to rejections made under 35 U.S.C. § 112, second paragraph in view of the Supreme Court holding in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831, 62 USPQ 2d 1705 (2002)

This memorandum clarifies Office policy with respect to rejections made under 35 U.S.C. § 112, second paragraph. The guidance provided herein is effective immediately and should be applied by all Office personnel. These changes will be published in the next revision of the MPEP.

As noted in MPEP § 217.02, during examination of claims for compliance with the requirement for definiteness under 35 U.S.C. § 112, second paragraph, some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. In reviewing a claim for compliance with 35 U.S.C. § 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the

art of its scope and, therefore, serves the notice function required by 35 U.S.C. § 112, second paragraph by providing clear warning to others as to what constitutes infringement of the patent. See *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, as rejection of the claim under 35 U.S.C. § 112, second paragraph would be appropriate. See *Morton Int'l, Inc. v. Cardinal Chemical Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993). Office policy is not to employ per se rules to make technical rejection. Examples of claim language which have been held to be indefinite set forth in MPEP § 2173.05(d) are fact specific and should not be applied as a per se rule. The test for definiteness under 35 U.S.C. § 112, second paragraph is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety travel chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ 2d 1081, 1088 (Fed. Cir. 1986).

If upon review of a claim in its entirety, the examiner concludes that a rejection under 35 U.S.C. § 112, second paragraph is appropriate, such as rejection should be made and an analysis as to why the phrase(s) used in the claim is "vague and indefinite" should be included in the Office action.

By providing an explanation as to the action taken, the examiner will enhance the clarity of the prosecution history record. As noted by the Supreme Court in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831, 1838, 62 USPQ2d 1705,

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1710 (2002), a clear and complete prosecution file record is important. With respect to amendments made to comply with the requirements of 35 U.S.C. § 112, the court stated that “[i]f a § 112 amendment is truly cosmetic, then it would not narrow the patent’s scope or raise an estoppel. On the other hand, if a § 112 amendment is necessary and narrows the patent’s scope—even if only for the purpose of better description—estoppel may apply.” *Id.*, at 1840, 62 USPQ2d at 1712. The court further stated the “when the court is unable to determine the purpose underlying a narrowing amendment – and hence a rationale for limiting the estoppel to the surrender of particular equivalents—the court should presume that the patentee surrendered all subject matter between the broader and the narrower language... the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question.” *Id.*, at 1842, 62 USPQ2d at 1713. Thus, when, whenever possible, the examiner should make the record clear by providing explicit reasoning for making or withdrawing any rejection related to 35 U.S.C. § 112, second paragraph.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11 to 15, 17 to 20, 22 to 31 are rejected, (as claims 1 to 24 of 10/318,963 have been rejected) under 35 U.S.C. 102(A/B) as being anticipated by each of:

Calderas et al (I) U.S. 5,431,940 (7/95);

Chang U.S. 5,336,510 (8/94);

Pflaumer et al U.S. 5,641,532 (6/97) ;

Montezinos (I) U.S. 5,792,502 (8/98);

Montezinos (II), U.S. 5,919,512; each describing an encompassed species of a beverage intended for oral administration, and an encompassed pH, containing an encompassed amount of an encompassed species of sodium or potassium polyphosphate, e.g. sodium hexametaphosphate, each reference silent on its inherent advantage, benefit, or property of preventing or treating dental erosion, each reference silent on "KITS" of it with printed matter (B) information on dental erosion benefit.

Claims 11 to 15, 17 to 20, 22 to 31 are rejected (as claims 1 to 24 of 10/318,963 have been rejected) under 35 U.S.C. 102(e) as being anticipated by

Cirigliano et al U.S. 6,022,576 (2/2000, filed 10/28/97);

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Kanayake et al U.S. 6,056,984 (5/2000, filed 8/10/99);

Sokolik et al U.S. 6,106,883 (8/2000, filed 10/25/95);

Smith et al (I) U.S. 6,126,980 (10/2000, to 2/28/95);

Calderas et al (II) U.S. 6,261,619 (7/2001 to 2/27/95);

Smith et al (II) U.S. 6,265,008 (7/2001 to 2/28/95);

Calderas et al (II) U.S. 6,268,003 each (2/2001, to 2/7/95);

Calderas et al (IV) U.S. 6,294,214 (9/2001, to 2/7/95);

Kearney et al U.S. 6,326,040 (12/2001, to 3/8/99); each antedating applicants January 21, 2000 filing date in describing an encompassed pH range beverage with an encompassed sodium or potassium polyphosphate e.g. sodium hexametaphosphate, but each silent on "KITS" of it with (B) printed matter information, on its inherent advantage, benefit or property re: dental erosion.

Claims 11 to 15, 17 to 20, 22 to 31 are rejected under 35 USC 103, ~~as stated~~ office action, over the foregoing prior art patents admittedly describing acidic pH fruit Juice and carbonated soft drink and tea beverages with added sodium hexametaphosphate, (polyphosphate, N=21) taken in view of McDonald or Muhler and one of Shibata et al McGaughey et al, or ~~a~~ Harris et al, each teaching polyphosphates being apt sources for the phosphate ion which Muhler and McDonald et al imparted to acidic beverages teaching phosphate ion imparts a dental tooth erosion benefit. McGaughey et al and Shibata et al are admitted prior art suggesting polyphosphate efficacy (at near neutral pH) set forth in the specification on page 2, lines 13 to 24.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11 to 15, 17 to 20, 22 to 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 24 of copending Application No. 10/318963 in view of failure of the written descriptions of both specifications to define the "metes and bounds" of the claim-recited term "about", as recited herein, therein in claim 1 "about 5.5" and in claim 23 herein "about 5" and failure of both specifications to define what precisely is a "KIT", as recited in claims 13 to 24 therein and herein, in claims 11 to 15, 17 to 20 and 22 in 09/489,310, failure of part (b) "information, etc" (in both) to constitute patentable novelty of the "KIT" claims under USPTO policy re: printed matter in MPEP (to treat or to prevent dental erosion, etc) (another reason: failure to accord weight to the preamble (purpose) (for oral ingestion) of otherwise old polyphosphate beverages, which beverage conventionally are orally ingested) under current decisional case law, in claims 1 to 12 therein and herein in claims 23 to 31 of 09/489310, the cited prior art describing encompassed species of beverages with encompassed species of sodium or potassium polyphosphate, such as sodium hexametaphosphate, said cited prior art being silent on

the inherent advantage, benefit, and/or property of such polyphosphates to treat or to prevent, dental erosion, their claimed new use "being applicants' method claims. An issue or ground of obviousness-type double patenting is seen presented by claims 1 to 24 therein and herein and copending claims 11 to 15, 17 to 20 and 22 to 31 of 09/489310.

This is a provisional obviousness-type double patenting rejection.

Applicants present application, Serial No. 09/489,310, filed January 21, 2000 (published August 1, 20002 as U.S. Patent application 2002 0102220) which contains method claims 23 to 31, drawn to the conventioned step of orally administering a beverage, to a mammal (the only known way to ingest a beverage) wherein the beverage is acidic, and has a pH of less than "about 5" (as compared to a pH of "less than 5", and contains a polyphosphate (N=about 7 to N=about 100) such as sodium hexametaphosphate (Examples 1 to 4 pages 22 to 24 herein sodium hexametaphosphate (N=21) in examples 3 and 4 on page 23 herein), same as in claims 1 to 12 therein, the only difference being that therein the polyphosphate beverage has a pH of "greater than about 5.5" (as compared to "greater than 5.5" (with no definition herein for "ABOUT"), and herein the polyphosphate beverage has a pH of less than about 5 (as compared to "less than 5") (with no definition therein for "about").

"KIT" claims 13 to 24 therein are the same as "KIT" claims 11 to 15, 17 to 20 and 22 of the present application Serial No. 09/489,310 with respect to (B) "information that use of the beverage provides treatment against dental erosion", supplied with the (A) polyphosphate beverage, as a "KIT".

There is no applicant supplied definition for "KIT" therein or herein, page 7, line 21 to 34 and page 5 lines 11 to 30 therein (and herein) which specification does define the terms "direction" "information" and "written" but both fail to provide a definition for the claimed term "KIT".

Applicants therein present claims 13 to 24 to a "KIT" comprising: (A) a "beverage" "according to claim 1," and (B) information that use of the beverage provides treatment against dental erosion, dental discoloration, or both.

Claims 1 to 12 therein are method claims reciting the step of orally administering, to a mammal, a beverage, (which appears to be in the only known way to ingest a beverage) comprising a sodium or potassium polyphosphate, (N=about 7 to N = about 100) such as sodium hexametaphosphate, (N=7), (n=17) (N=21), (according to examples 1 to 4 on pages 23 to 25) which ^{phosphates} polyphates as background information, have, admittedly been added to beverages (see: the recitals therein of page 4, lines 5,6,8 to 10, (polyphosphates previously described added to tap or bottled water, and previously described to fortify fruit drinks orange juice, apple juice containing calcium or other minerals, and the recitals therein of page 3, lines 6 to 10, Smith Kline Beecham WO 01/72144 describing encompassed species of polyphosphates (N= 7 to 30, same as therein), to alleviate tooth damage (same as herein) in beverages, (same as herein) having a pH of about 5.5 (same as herein) or lower (pH 2.5 to 5.5) (as herein), and Reussner et al (1975) (page 2 line 33 to page 3 line 5, who anticipate applicants herein in teaching that the phosphate ion (whether or not from encompassed polyphosphate

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sources) is (or may not be) completely protective against acidic beverage dental erosion.

It is the policy of the USPTO to consult or resort to dictionary definitions of terms when applicants fail to provide their definition in the written description of the specification.

There is no written description definition herein, or therein, of the claimed term "KIT" as recited in claims 13 to 24 therein (See page 8 line 31 page 9, line 9, and page 6, lines 19 to 35 which do define "information" "written" and "direction", but fail to provide, a definition, or to define, applicants' "KIT").

The "beverage" claimed by applicants therein can be "milk" (page 13, line 32 to page 14, line 5) or tea, or juice, etc with neutral pH, ("non-acidic") but cannot be (as herein) "acidic beverages" (page 1, line 21 to page 2, line 6, page 3, lines 11 to 15 page 4, lines 10 to 12, page 20, lines 4 to 6, which admittedly cause dental erosion).

There are more than one dictionary definitions for the term "KIT".

DICTIONARY DEFINITIONS: for the term "KIT".

"Kit": a collection of articles; or the container containing these, or this with its contents;

"KIT": the outfit of tools required by a workman;

"KIT": a collection of things a group of things; number of things viewed as a whole: a set, lot, collection; esp. the whole kit (and caboodle);

"KIT": a shortened form of kitten; a kitten.

"KIT" a collection of articles and appliances for any special purpose: and outfit.

"KIT": a set of tools or implements.

"KIT": a set of parts to be assembled.

"KIT": a packaged collection of related material

"KIT": a container for any of such sets or collections.

"KIT" a young or undersized fur bearing animal.

Thus a reasonable interpretation of these "KIT" claims (therein) encompassing a milk beverage, leads to the distressing implication, that applicants "KIT" claims (therein) are intended to exclude, or to deprive, all others from putting milk in a kitten (!) or other young undersized fur bearing animal), (if "KIT" can be defined as a shortened form of kitten), or else reads on a carton of milk with polyphosphate or hexametaphosphate added, with other printed information on the milk carton and considering the policy of the USPTO in giving no weight to (B) "information on it by adding this dental erosion benefit information (B) thereto.

A recent June 25, 2003 Memorandum to Patent Examiners from Stephen Kunin, Deputy commissioner for Patent Examination Policy, notes that MPEP 2111 is material releant and important to the issue of claim interpretation of the claim – recited terms "about" and "KIT", which have not been defined in the written description of this specification.

Memorandum

Date: June 25, 2003

To: Technology Center Directors

Patent Examining Corps

From: Stephen G. Kunin
Deputy Commissioner for Patent Examination Policy

Subject: Claim interpretation and procedures to handle applicant's reply arguing that a term in the claim is limited to the special definition provided in the written description

This memorandum sets forth guidance for claim interpretation and the procedures to handle an applicant's reply arguing that a term in the claim is limited to the special definition provided in the written description.

Claim Interpretation

As noted in MPEP § 211, during patent examination, claims are given their broadest reasonable interpretation consistent with the specification. It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim. However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F. 3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994); *Intervet America Inc. v. Kee-Vet Lab. Inc.*, 887 F.2d 1050, 1053, 12 USPQ2d 1474, 1476 (Fed. Cir. 1989).

Words of the claim are generally given their ordinary and customary meaning unless it appears from the written description that they were used differently by the applicant.

Where an applicant chooses to be his or her own lexicographer and defines terms with special meanings, he or she must set out the special definition explicitly and with

“reasonable clarity, deliberateness, and precision” in the disclosure to give one of ordinary skill in the art notice of the change. See *Teleflex Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1325, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP § 2111.01 Pursuant to 35 U.S.C. § 112, 2nd paragraph, “[I]t is applicant’s burden to precisely define the invention, and not the [examiner’s].” In re Morris, 127 F.3d 1048, 1056, 44 USPQ2s 1023, 1029 (Fed. Cir. 1997). Therefore, it would not be proper for the examiner to give words of the claim special meaning when no such special meaning has been defined by the applicant in the written description. Furthermore, it would not be proper for the examiner to allow a claim and issue the application with an examiner’s statement of reasons for allowance setting the special definition given to the words of the claim when no such special definition has been defined by the applicant in the written description.

Procedures to handle applicant’s reply arguing that a term in the claim is limited to the special definition provided in the written description:

If during examination of an application, the examiner has given a term in the claim its plain meaning as interpreted by one of ordinary skill in the art and applied prior art accordingly, and in applicant’s reply pursuant to 37 CFR § 1.111, applicant argues that the term in the claim is limited to the special definition set forth in the written description (by referring specifically to the page and line/paragraph number of the specification), the examiner must review the written description to determine whether applicant’s argument has support in the written description. It is not appropriate to merely accept applicant’s

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argument without reviewing the written description to determine whether applicant's argument has support. If applicant's argument is persuasive, that is, the written description explicitly and clearly set forth a special definition for the term in the claim, the examiner should reconsider the rejection in view of applicant's reply. If the previous rejection is withdrawn, the examiner must provide in the next Office communication the reasons why the previous rejection is withdrawn by referring specifically to the page(s) and line(s) of applicant's remarks that form the basis for withdrawing the rejection. See MPEP § 707.07(f).

If upon review of the written description, the examiner determines that no special definition is set forth by the applicant and an amendment to include such a special definition in the claims and/or the written description would constitute new matter pursuant to 35 U.S.C. § 132 (a), the examiner should maintain the previous rejection and provide an explanation to the applicant in the next Office communication. It would not be proper for the examiner to allow a claim and issue the application with an examiner's statement of reasons for allowance setting forth the special definition given to the words of the claim when no such special definition has been defined by the applicant in the written description. Note that where the definition set forth in the written description is merely exemplary (where applicant used the phrase "for example"), the examiner should not consider this as a special definition and an explanation should be provided in the next Office communication as to the reasons why applicant's argument is not persuasive.

It upon review of the written description, the examiner determines that applicant's argument is supported by the written description and the claims would be allowable over the prior art but the special definition for the term in the claim as noted in applicant's arguments is not explicitly or clearly stated in the written description, and an amendment to the written description to explicitly and clearly include such a special definition would **not** constitute new matter, the examiner should contact the applicant and request approval for an examiner's amendment. It would be appropriate in such a case to include an examiner's statement of reasons for allowance to ensure that the record is clear as to the reasons why the claims are allowable over the prior art of record. See MPEP § 1302.14. One of the reasons for requiring an amendment to the written description to explicitly set forth the special definition is so that when the patent issues, notice would be provided to the public as to the scope of the patentee's rights without the public having to check the prosecution history for the information. "KITS" are presumed to be packaging of assembled materials, components etc. with instructions (printed matter) for the user.

Prior to setting forth the Office Action, for clarity of prosecution, the following is noted about printed matter:

The printed matter on a label or package insert in a "KIT" does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition, or article of manufacture.

See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, it is stated that: Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned...In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Also see In re Venezia 189 USPQ 49 (CCPA 1976), where "kits" are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC) 217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The claimed articles in the "kit" remain fully functional absent the labeling or printed instructions for use.

It is further noted that the written material in the kit instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a).

Thus the instructions for use included in a "kit" or article manufacture constitute and "intended use" for that kit or article of manufacture.

Intended use does not impart patentable weight to a product. See MPEP 2111.03:

Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963)

In the instant case, the kit claims are drawn to an old composition article of manufacture which further comprises "information" (printed matter) labeling. The intended use which is recited on the label or package or "kit" insert lacks a functional relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, the old article or old composition in the "kit" can still be used by the skilled artisan for other purposes. Therefore the "kit" of old article or composition which are comprised within the article of manufacture are unpatentable over the prior art because they function equally effectively with or without the labeling and accordingly no functional relationship exists between the instructions for use and the composition.

Thus the claims are addressed as being drawn to an article of manufacture comprising an old composition and a package insert, the instructions on the insert bearing no patentable weight with regard to double patenting, 102, and 103 rejections.

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Claims 11 to 15, 17 to 20 and 22 to 31 have been, and are rejected under 35 U.S.C. 103(a) as being unpatentable over (details as noted above) describing such polyphosphates as sodium hexameta phosphate in such pH acidic beverages, (but silent on tooth erosion benefit) taken with Mc Donald et al or Muhler (details below) polyphosphates being well-known to persons skilled in this art as an apt source for phosphate ions.

Mc Donald et al (1973) J. Dent. Res. 552 (2) : 211-216 not only teach the technical problem confronting applicants, namely that acidic beverages can cause dental erosion but also suggest applicants solution to this problem, adding $\text{Na H}_2 \text{Po}_4$ (a source of phosphate) (4.0 mg. phosphate per milliliter) to these acidic beverages reduced dental erosion (damage to dental enamel), concluding, on page 216, "the results of these studies suggest the deleterious potential of these acidic beverages to produce erosion of dental enamel and to cause dissolution of enamel, regardless of the presence or absence of sucrose. The addition of phosphate reduced the magnitude of the damage to enamel. The findings with regard to experimental caries indicate that the cariogenic properties of a typical acid containing beverage can be negated completely by the addition of phosphate.

Muhler (Indiana University Foundation) South Africa 694743 (1969) contains the same solution to the same technical problem-to add phosphate ions from $\text{Na H}_2 \text{Po}_4$ (monosodium dihydrogen phosphate) to acidic beverages to reduce their dental enamel erosion causing property.

Sodium and Potassium Hexametaphosphate (or polyphosphate) are well-known as an apt source of phosphate ions (as see Shibata et al, McGaughey et al and Harris et al) and encompassed species of such polyphosphates in encompassed species of orally ingestable beverages, are described in the Examiner relied-upon prior art.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11 to 15, 17 to 20, 22 to 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 6 of U.S. Patent No. 5,431,940. Although the conflicting claims are not identical, they are not patentably distinct from each other because no weight is given to the (B) information (printed matter) in the KIT of the same (A) acidic beverage with the same sodium hexametaphosphate polyphosphate, the method of "treating (protecting against erosion) is the same oral ingestion of the same beverage.

Claims 11 to 15, 17 to 20, 22 to 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to

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30 of U.S. Patent No. 5,641,532. Although the conflicting claims are not identical, they are not patentably distinct from each other because same reason as above.

Claims 11 to 15, 17 to 20, 22 to 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 21 of U.S. Patent No. 5,792,502. Although the conflicting claims are not identical, they are not patentably distinct from each other because same reason as above.

Claims 11 to 15, 17 to 20, 22 to 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 15 of U.S. Patent No. 5,919,512. Although the conflicting claims are not identical, they are not patentably distinct from each other because same reason as above.

Claims 11 to 15, 17 to 20, 22 to 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 27 of U.S. Patent No. 6,126,980. Although the conflicting claims are not identical, they are not patentably distinct from each other because same reason as above.

Claims 11 to 15, 17 to 20 and 22 to 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 7 of U.S. Patent No. 6,261,619. Although the conflicting claims are not identical, they are not patentably distinct from each other because same reason as above.

Claims 11 to 15, 17 to 20, 22 to 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 16 of U.S. Patent No. 6,265,008. Although the conflicting claims are not identical, they are not patentably distinct from each other because same reason as above.

Claims 11 to 15, 17 to 20, 22 to 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 13 of U.S. Patent No. 6,268,003. Although the conflicting claims are not identical, they are not patentably distinct from each other because same reason as above.

Claims 11 to 15, 17 to 20, 22 to 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 22 of U.S. Patent No. 6,294,214. Although the conflicting claims are not identical, they are not patentably distinct from each other because same reason as above.

Claims 11 to 15, 17 to 20, 22 to 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 17 of U.S. Patent No. 6,326,040. Although the conflicting claims are not identical, they are not patentably distinct from each other because same reason as above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday, Tuesday and Thursday from 6 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Shep Rose

**SHEP K. ROSE
PRIMARY EXAMINER**

Rose/LR
August 28, 2003